NIBIB

NATIONAL INSTITUTE OF
BIOMEDICAL IMAGING AND
BIOENGINEERING

STRATEGIC PLAN I

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

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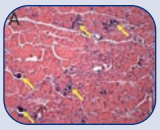

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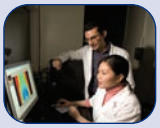

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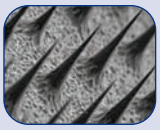

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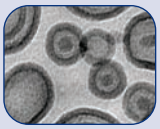

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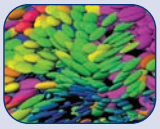

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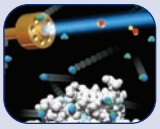

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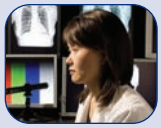

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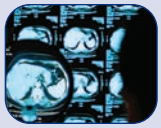

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STRATEGIC PLAN I

Message from the Director

As the first Director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB), I am pleased to present our inaugural Strategic Plan. This plan is designed to (1) define key goals, (2) optimize the use of resources, and (3) install tools and processes for smart management in order to help achieve our mission and to realize our vision. It is our hope that we will greatly improve health care in our nation and the world through the development and successful application of emerging biomedical technologies.

The goals, strategies, and objectives that are outlined, address the opportunities and challenges facing our Institute. Through strategic planning retreats and group discussions, an NIBIB working group of senior management identified scientific priorities, opportunities, and challenges across the programs of the Institute. This group collaborated with our National Advisory Council, the scientific community, professional organizations, and the public to create this document. For example, the NIBIB hosted several broadly attended scientific planning meetings to obtain feedback from the research community.

The Strategic Plan complements and builds upon planning processes that are already underway within the NIBIB. By design, the plan is not a budget document. Instead, it targets the most promising research goals that might reasonably be achieved within a 5-year time frame and focuses on long-term, trans-agency scientific themes.

Although the initial document is designed to be a multi-year plan, we consider it a work in progress. We will revisit and refine the plan on an annual basis. Goals, strategies, and objectives will continue to evolve and mature through the NIBIB's iterative planning process, conducted in conjunction with our National Advisory Council and our stakeholders.

Sincerely,

Roderic I. Pettigrew, Ph.D., M.D.
Director, National Institute of
Biomedical Imaging and Bioengineering

Our Mission

Improve human health by leading the development and accelerating the application of biomedical technologies.

The Institute is committed to integrating the engineering and physical sciences with the life sciences to advance basic research and medical care.

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) is the newest of the National Institutes of Health (NIH) member Institutes and Centers. Public Law 106-580, which was signed into law on December 29, 2000, authorized the establishment of the NIBIB to provide a research home for the development and application of new biomedical technologies and techniques for the improved delivery of health care in the 21st century. The NIBIB brings together the research communities of biomedical imaging, bioengineering, the physical sciences and the life sciences to advance human health by improving the quality of life and reducing the burden of disease.

Statement of Commitment

The National Institute of Biomedical Imaging and Bioengineering is entrusted by our Nation's citizens to improve the health of all people. The Institute is committed to driving medical innovation and expanding biomedical knowledge for this and future generations.

The Scope of NIBIB's Mission

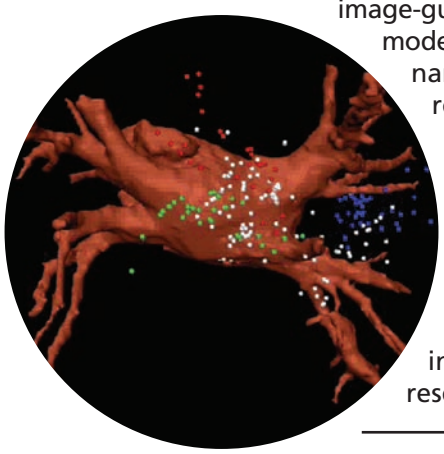
NIBIB's mission statement, which reflects the Institute's statutory mandate, encompasses the following activities:

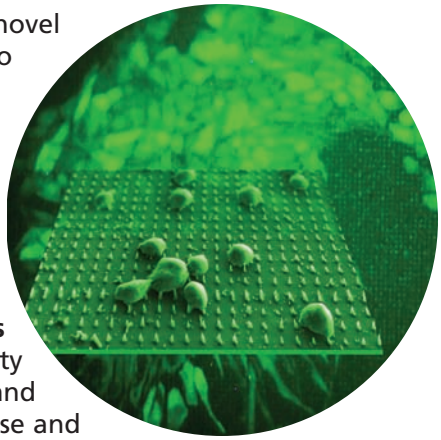
1. **Develop new biomedical imaging and bioengineering techniques and devices** to better understand disease and to fundamentally improve the diagnosis, treatment, and prevention of disease.

2. **Enhance existing imaging and bioengineering modalities**, for example, by supporting advances that reduce cost or improve function, by exploring new uses of existing technologies, or by combining technologies for new purposes.

3. **Support related research in the engineering, physical, and mathematical sciences** through collaborations with other NIH Institutes and Centers and other Federal agencies, including the Department of Defense (DoD), the Department of Energy (DOE), the Food and Drug Administration (FDA), the National Institute of Standards and Technology (NIST), the National Science Foundation (NSF), and the National Aeronautics and Space Administration (NASA).

4. **Encourage interdisciplinary research areas**, such as molecular imaging, biophotonics, bioinformatics, biomaterials, biosensors, computational biology, image-guided interventions, modeling, biomechanics, nanotechnology, rehabilitation technology, target-specific imaging agents, telemedicine, and tissue engineering. The NIBIB will support interdisciplinary research teams through existing and novel mechanisms, while also sustaining individual investigator-initiated research.



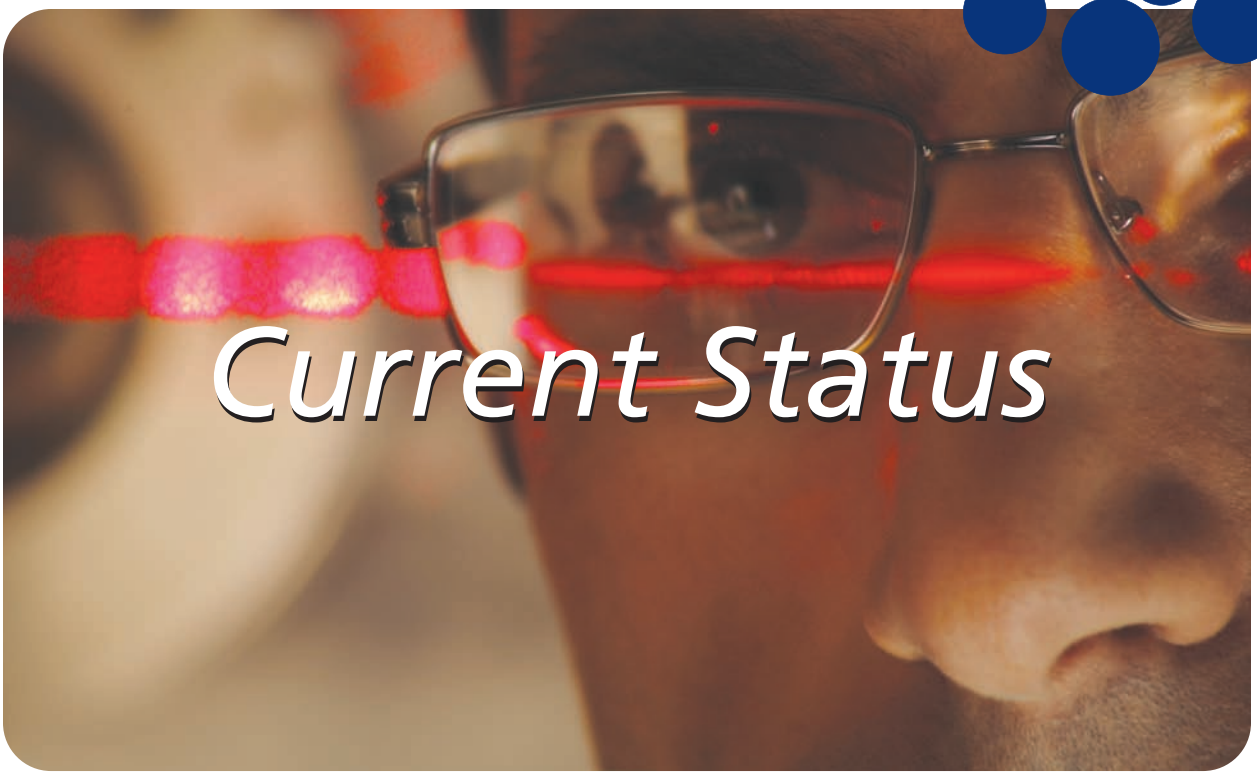


5. **Support studies to assess the effectiveness of new materials, processes, devices, and procedures** to determine the quality of a new technology and its most appropriate use and to guide the development of the next generation of technologies. To provide the necessary mix of technical and clinical expertise in evaluation studies, the NIBIB will collaborate with disease-specific Institutes at the NIH and other Federal agencies.

6. **Develop technologies for early disease detection and assessment of health status.** Early detection and treatment of disease, before noticeable symptoms appear, has the potential to greatly reduce morbidity, mortality, and the cost of disease.

7. **Develop advanced imaging and engineering techniques for conducting biomedical research at multiple scales**, from the molecular and genetic to the whole-body level and to entire populations. The NIBIB will also support efforts to integrate data from these different levels, which may provide unique insights that could not be achieved *via* single-scale approaches.

Beyond the research activities outlined above, the NIBIB will support training and education as well as the dissemination of health information to physicians, other health care providers, and the general public. In addition, the NIBIB will consider ethical issues in the use of new and emerging technologies for diagnosis and treatment.



Current Status

In late 2004, the NIBIB embarked on a strategic planning process to identify long-term goals for the next 3 to 5 years. As an initial step in planning for the future, the group first considered the current state of the science within the Institute's mission and the Institute's progress in leading advances in these areas.

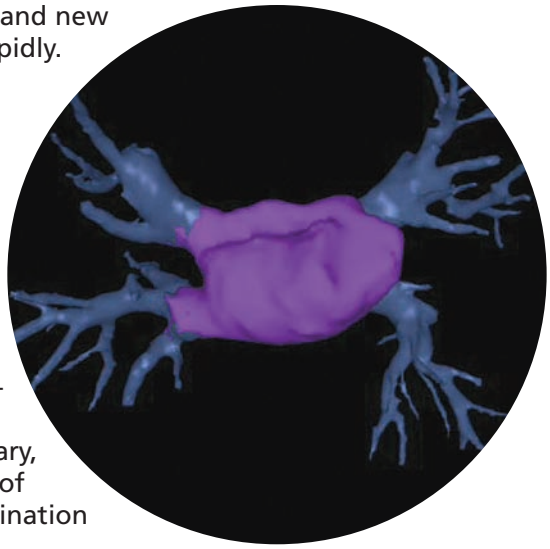
In the last quarter century, there has been a revolution that has brought engineering and the physical sciences to greater prominence in the biomedical field. This revolution has had, and will continue to have, significant ramifications for medical practice. For example, sophisticated imaging technologies have reduced the need for exploratory surgery. Implanted therapeutic devices are increasingly used as effective treatments for cardiac rhythm abnormalities, joint dysfunction, and impaired neurological function.

These and other advances have led to the growth of the medical device and diagnostics industry with worldwide sales approaching $200 billion. This industry stimulates continued advances in new treatments and therapies by investing approximately 7 percent of revenues in research and development.

Bioengineering has emerged as a vibrant discipline. Today there are more than 65 bioengineering departments at U.S. colleges and universities. There is also an increased emphasis on biomedical science in engineering and physical science departments. The fields of bioengineering and imaging will be further enhanced by multidisciplinary input from chemical, electrical, and mechanical engineers, as well as chemists and physicists.

Biomedical imaging is now an indispensable tool for the diagnosis and treatment of a variety of diseases. In the early twentieth century, incremental advances in imaging were achieved at a

relatively slow rate. However, in the last 40 years, improvements and new discoveries in imaging technologies have occurred much more rapidly. The plain x-rays of over 100 years ago have been replaced by the discovery of ultrasonic, radioisotopic, and optical imaging, computed tomography, and magnetic resonance imaging (MRI). In addition, the scalability of imaging methods is growing – ranging from visualization of the whole body and individual organs, to cellular, sub-cellular, molecular, and atomic levels.



The creation of the NIBIB occurred at an extraordinary time. Discoveries in biomedical imaging and bioengineering have already had an enormous impact on health care. These disciplines are ripe with opportunities for major scientific advances. The NIBIB is well-positioned to further advance these fields through support of technology development; promotion of integrated, multidisciplinary, and collaborative approaches to biomedical research; leadership of initiatives on health disparities and the aging population; dissemination of research findings; and development of training programs.

The NIBIB is uniquely suited to support technology development. Unlike any other NIH Institute or Center, the NIBIB's mission is focused on emerging technology development. The Institute has a mandate to enable and promote fundamental discoveries, and to support the design, development, translation, and assessment of technological capabilities in biomedical imaging and bioengineering.

The NIBIB promotes integrated, multidisciplinary, and collaborative approaches to biomedical research. The NIBIB coordinates with other Federal agencies and NIH Institutes and Centers to support research and research training through existing NIH funding mechanisms. NIBIB leads in exploring novel approaches to support interdisciplinary research and training.

The NIBIB addresses our Nation's pressing health concerns, including America's aging population and health disparities. The NIBIB provides leadership to develop cross-cutting research and training in biomedical imaging and bioengineering to reduce health disparities.

The NIBIB informs the public about research. The NIBIB disseminates research findings to physicians, other health care providers, the research community, and the general public. Through the Web site, publications, and other outreach efforts, the Institute communicates how its research agenda dramatically advances the Nation's health.

The NIBIB is committed to the advancement of bioengineering, biomedical imaging, and the quantitative sciences in biomedicine through comprehensive training programs. The NIBIB provides training opportunities in bioengineering and biomedical imaging *via* existing NIH mechanisms and new approaches. The Institute actively reaches out to students to disseminate information about these programs. NIBIB-funded training programs are designed to fill critical gaps in career continuums and to enhance participation of underrepresented populations.

The NIBIB is a proper steward of public trust, and allocates resources responsibly. The NIBIB properly manages resources and seeks opportunities to leverage funding through joint efforts with industry, other NIH Institutes and Centers, and other Federal agencies. The Institute assesses the actual and potential outcomes of supported research to ensure the most effective allocation of resources. The NIBIB also considers ethical issues in the use of new and emerging technologies for diagnosis and treatment.

Our Vision

We will profoundly change health care.

NIBIB will push the frontiers of health care technology to make the possible a reality.

The NIBIB will lead the development of revolutionary technologies that will change the face of medical care across America and around the world. The Institute will partner with industry, academia, and other Federal agencies to provide innovative and safe biomedical technologies that improve public health and reduce suffering due to injury and illness. The NIBIB will unite the engineering and physical sciences with the life sciences to bring forth new ways of thinking that will accelerate discovery and technology development. With a global vision and a public health mission, the Institute will aim for personalized health care, early detection of disease, and treatments that are minimally-invasive, cost-effective and widely accessible.

Among the advances that NIBIB envisions are:

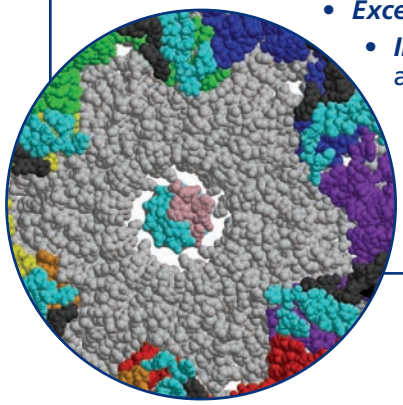
- Technologies that will detect early, preclinical, molecular events to identify patients at risk. This would allow the prediction of disease and pre-emptive or preventative steps to be taken. For example, molecular imaging and high-throughput technologies to evaluate genes for screening disease would be one such technology.
- Smart sensors that will use chemical and physiologic signals from the body to release drugs at the right site, at the right time, and at the right dose. For example, glucose-activated insulin-delivery systems that will effectively replace the function of the pancreas for people with diabetes.
- Living engineered tissue capable of growth and normal function to repair or regenerate damaged tissues or organs resulting from heart attack, kidney failure, arthritis, trauma, or other conditions; to eliminate the need for repeated surgeries; to overcome the current limitations of artificial organs and joints; and to alleviate the shortage of organs for transplantation.

- Minimally-invasive, image-guided, or robotic-assisted micro-surgery that will become the standard of care for surgical procedures.
- Telemedicine advances to broaden access to health care among the underserved. Portable diagnostic devices will enable gathering of physiological, biochemical, and diagnostic image data non-invasively in rural and non-hospital settings. Transmission of this data in real time to major health care centers will be possible through nationally and internationally managed medical networks.
- Personalized medical therapy with drug selection and dosing based on the unique biochemical fingerprints of each patient's genetics. Image-guided techniques will facilitate early diagnosis and more precise drug delivery. The drugs themselves will be encoded for direct delivery to specific cells or organs as well as imaging beacons capable of reporting successful interaction of the drug with diseased cells.
- New approaches that will facilitate the quantitative understanding of the relationship among elements of complex biological systems and allow for integration across biological scales, from gene to organ to the whole body. These approaches will be used to predict biological and pathological events.

To honor the public trust, the NIBIB will push toward the full realization of these and other medical technologies, many yet undiscovered. The Institute envisions a day when disease is preventable, health is predictable, and the treatments of today are a thing of the past.

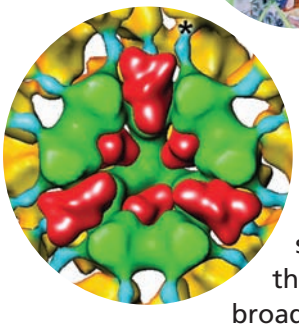
Values

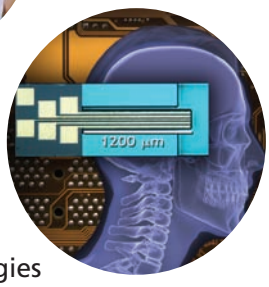
The NIBIB has a commitment to continually revolutionize medical technology to improve human health worldwide. Our success in this mission is based upon the acceptance of shared core values:



- ***Excellence.*** We consistently seek and achieve the best.
- ***Innovation.*** We are willing to take risks, readily embrace new approaches, and actively pursue ground-breaking ideas.
- ***Integrity.*** We act as ethical, open, and honest stewards of the public trust.
- ***Partnership.*** We work in collaborative efforts to maximize the beneficial impact on human health.

THE PLAN: GOALS, STRATEGIES, AND OBJECTIVES





To accomplish NIBIB's mission, the Institute has developed a series of goals, strategies, and objectives designed to maximize the Institute's impact on human health. This framework will shape the Institute's direction over the next several years and determine how NIBIB will allocate resources to support and enhance scientific research. In implementing this plan, the Institute will seek continuous stakeholder input and make adjustments as warranted. The Institute will further leverage its intellectual and financial resources through joint ventures with the private sector and other Federal agencies. The NIBIB will use tools and processes for effective management.

The goals outlined in the plan have been broadly grouped into areas of scientific and operational emphasis. Goals describe the state the Institute could achieve with the successful implementation of this plan. Each goal has an associated set of strategies that are the broad actions the Institute will take to effectively pursue the goal. Each goal and set of strategies also has an associated set of objectives. Objectives provide some measures of progress toward achieving a goal and can be monitored to ensure that appropriate progress is being made.

Although the initial document is designed to be a multi-year plan, we consider it to be a living document and plan to revisit it annually. Goals, strategies, and objectives will continue to evolve through NIBIB's iterative planning and evaluation process, conducted in conjunction with its National Advisory Council and stakeholders.

AREAS OF SCIENTIFIC EMPHASIS

Interdisciplinary Research

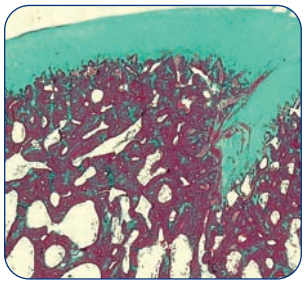
Goal 1

A strong extramural research community focused on discovery, development, and application of science and technology to improve health.

Some important areas of research in the engineering, physical, and imaging sciences have not been traditionally well represented at the NIH. The NIBIB will dedicate the majority of its resources to support the research areas that fall within our mission. With an emphasis on interdisciplinary activities, our portfolio will include a number of multiple-investigator grants and interdisciplinary projects, as well as the more traditional single-investigator R01 grants.

Strategies

- Set priorities based on scientific merit, scientific opportunities, public health needs, and the unique mission of the NIBIB.
- Support individual investigator-initiated projects that advance the NIBIB mission.
- Encourage team science.
- Promote systems engineering and the integration of multiple engineering disciplines to enhance novel technology development.
- Encourage and develop new investigators in the expanding research fields of engineering, physical, and imaging sciences.
- Encourage international collaboration.
- Identify and develop cross-Institute and cross-agency mechanisms to co-fund projects with significant technology components.



New Hope for Old Joints

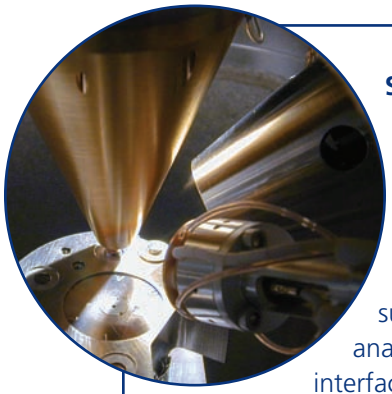
Damaged cartilage in knees and joints, caused by traumatic injury or the regular wear and tear of age, is nearly impossible for the body to repair on its own. Unlike other tissues, cartilage lacks the blood vessels that deliver nutrients and other healing substances to damaged regions.

Dr. Lori Setton, associate professor and director of the cartilage mechanics and tissue engineering laboratory at Duke University, has produced a biomaterial that could help the body use its own resources to replenish damaged cartilage. The versatile liquid polymer gel can be injected and "poured" into torn cartilage tissue, where the liquid gel adapts to the contours and size of the cartilage tear. The biomaterial solidifies in 30 seconds when exposed to laser light and forms a scaffold for the body's own chondrocyte cells, which help to rebuild cartilage.

"We hope the new procedure will achieve about the same success, or better, than cartilage cell transplantation," says Setton. "It should be better integrated, more durable, and offer a more rapid recovery. The procedure also would be less costly than cell transplantation."

Objectives

- The research community in bioengineering, biomedical imaging, and interdisciplinary science research is enlarged and strengthened.
- The number of research projects at the interface of the physical and life sciences increases.
- The NIBIB research portfolio is balanced between basic discovery research and the development and application of emerging technologies.
- NIBIB resources result in substantial numbers of new investigators in the interdisciplinary fields of bioengineering and biomedical imaging.



State-of-the-Art Surface Analysis

NIBIB supports a large network of Biomedical Technology Resource Centers, which ensure that NIH-supported scientists can gain access to the newest and most advanced technologies, techniques, and methodologies. One such center, The National ESCA and Surface Analysis Center for Biomedical Problems (NESAC/BIO), provides the biomedical research community with state-of-the-art surface analysis expertise, instrumentation, experimental protocols, and data analysis methods to address biological and medical problems involving surfaces and interface regions. The long-term goal of the center is to develop high-resolution analytical techniques to characterize the nanoscale structure, orientation, and dynamics of peptides and proteins on nanoparticle surfaces as well as other surfaces.

Since the nature of a surface strongly influences the composition and recognizability of the biomolecules and cells that interact with materials, understanding the structure of surfaces and the nature of adsorbed biomolecules are key to understanding interfacial biology for both *in vivo* (e.g., implanted biomedical devices) and *in vitro* (e.g., DNA microarrays) applications. For example, changes in the nanoscale or molecular structure of proteins can occur when they interact and become attached to a surface. For this reason, NESAC/BIO offers a suite of complementary techniques that provide a comprehensive understanding of the nanoscale structure of surface bound proteins. Electron spectroscopy for chemical analysis, time-of-flight static secondary ion mass spectrometry, scanning force microscopy, near edge X-ray absorption fine structure, and vibrational spectroscopy are used to provide information on surface composition, structure, spatial distribution, and orientation of biomaterials and adsorbed biomolecules.

Areas of investigation include biosensors, nanobiology, tissue engineering, cell growth surfaces with peptides, lipid surfaces, DNA arrays, and the attachment of proteins and peptides to the surface of nanoparticles for the early detection and treatment of cancer. Since protein-surface interactions are an integral part of many biomedical applications, developing the ability to characterize and control the surface structure of proteins will have widespread impact in biology and medicine.

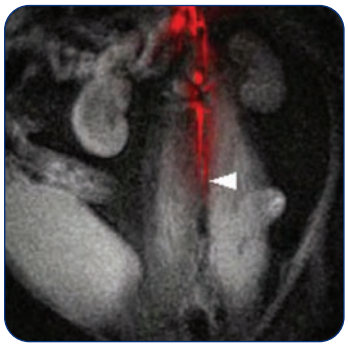
Goal 2

Targeted research programs in areas of special opportunity or need that take advantage of novel technological advances and scientific discoveries.

The NIBIB will target specific biomedical research areas to take advantage of novel technological advances and discoveries in the physical sciences; address public health needs and priorities; and solve challenges that prevent significant advances in health care. Achievement of this goal requires information about emerging technologies and scientific advances, challenges, and public health needs; collaborations with industry, other NIH Institutes and Centers, other Federal agencies, and academia; a dedicated budget; and leveraging of funding and research resources to compensate for budget constraints.

Strategies

- Identify and support areas of particular promise or special need and a select group of large-scale, high-impact projects.
- Utilize collaborations between intramural and extramural divisions.
- Provide a set-aside budget for targeted activities.
- Leverage funds and resources through joint ventures.



Visualizing Blocked Arteries

One of the most common procedures to treat clogged arteries is catheterization. Physicians insert a thin tube into the blocked vessel and, using X-rays and imaging dyes, guide the catheter to the obstruction. When a new blood clot blocks an artery, guide wires typically cross easily through the fresh clot with blind probing, and the clot can be eliminated. However, because imaging dyes do not penetrate chronically blocked vessels, these blockages remain largely invisible on X-rays. Individuals with chronic blockages are usually treated with more invasive bypass surgery.

An alternative that would improve patient care and reduce medical costs is under development at Stanford University. Lead investigator John Pauly and his colleagues are pursuing a real-time interactive magnetic resonance imaging system. The system has the potential to fully visualize blockages as well as surrounding tissue so that physicians can guide the probe directly to blocked regions and easily eliminate clots. MRI provides excellent tissue contrast and can image both the vessel core and the vessel wall without relying on contrast agents or ionizing radiation.

Objectives

- Selected projects that provide profound improvements in medical care are designed and implemented.
- Program announcements or other initiatives that target critical areas such as bioinformatics and computational modeling, tissue engineering, sensors and measurement instruments, molecular imaging, image-guided interventions, and low-cost imaging are released.

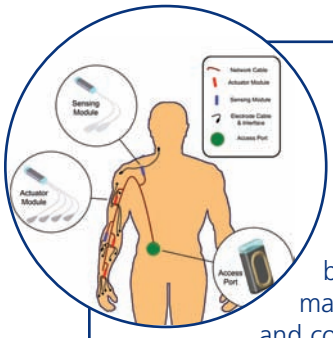
Goal 3

Accelerated translation of promising technologies to improve human health.

Scientific knowledge and discoveries are increasing at a tremendous rate. However, efforts to translate these findings into new therapies, diagnostics, and preventative agents are often obstructed. The NIBIB supports the development of novel technologies and the subsequent translation of those technologies into applications for the benefit of public health. In accordance with the Congressional mandate that the NIBIB "facilitate the transfer of technologies to medical applications," the Institute is committed to the following strategies and objectives.

Strategies

- Include validation, evaluation, and effectiveness studies as objectives in initiatives for technology research.
- Address intellectual property and regulatory issues.
- Promote entrepreneurial training opportunities for students and academic researchers.
- Promote translational research.
- Collaborate and leverage resources with stakeholders – including industry, regulatory agencies, academia, and professional organizations – to address barriers and capitalize on mutually beneficial opportunities.



Wired for Movement

For stroke survivors or individuals with spinal cord injuries regaining control over their limbs can be a daunting task. Neuroprosthetic devices are powerful tools that enable these individuals to breathe, stand, walk, reach, grasp, and eliminate. However, each control system must be customized for a specific function such as breathing or standing and does not communicate with other systems an individual may need. Movement is limited because users are tethered to external power sources and computer links.

A Biomedical Research Partnership (BRP) project, led by Hunter Peckham at Case Western Reserve University, and sponsored by NIBIB and the National Institute of Neurological Disorders and Stroke, offers a new approach to neuroprosthetic devices. The networked neuroprosthetic system (NNPS) is based on a web of implanted modules that link to a replaceable centralized power source. Each module can process information, communicate with other modules through the network cable, and is reprogrammable *via* a central wireless link attached to the user's skin. Because of the system's flexibility technicians can tailor each NNPS to a user's specific needs.

With the power pack, sensors, and computer processors surgically implanted, individuals using the networked system are free of all external devices during normal activities. The network can be upgraded after initial implantation without removing any components. Researchers anticipate each network could operate in the body for 50 years.

Objectives

- An NIBIB office to foster the translation of science to products and to cultivate industrial relations is created.
- A consortium of Federal agencies, industry, and academia is established to address specific challenges to bringing new technologies to market.
- Information is disseminated about NIBIB-supported discoveries and innovations that possess market potential.
- Technology translation sessions are held periodically with grantees, industry, academic technology transfer experts, other NIH Institutes and Centers, other Federal agencies, and private foundations.
- A database is developed to track products resulting from NIBIB-supported research and periodic studies are conducted to assess technology development and transfer from NIBIB-funded grants.
- A joint initiative with other Federal agencies promoting entrepreneurship in universities is launched.
- Collaborations are established with appropriate agencies – such as NIST and FDA – to contribute to the development of standards for biomedical technologies.
- Research that evaluates the impact of technology performance data on the outcome of research studies and clinical trials is promoted.

Goal 4

Reduced health disparities through new and affordable medical technologies.

As the NIBIB plans programs to address health disparities, one broad area of exploration is the potential of various technologies and reductions in the costs of these technologies to improve access for underserved populations. Another approach will be to investigate the potential for imaging and bioengineering to improve the prevention, diagnosis, and treatment of diseases for which these disparities are most pronounced. These strategies are further elaborated in the NIBIB submission for the NIH Comprehensive Strategic Plan and Budget to Reduce and Ultimately Eliminate Health Disparities Fiscal Years 2002-2006 (appendix A).

Strategies

- Promote research on the development of new and affordable medical technologies.
- Partner with industry to reduce the cost of existing medical technologies and to make them more widely available.
- Increase dissemination of information on NIBIB and research advances to underserved communities.
- Educate underserved patient populations on disease management and quality care.

Controlling Weight with Cable

A sedentary lifestyle is one of the causes of the growing obesity and the type 2 diabetes epidemic in America. Weight loss has been shown to improve diabetes outcomes, reduce the need for medication, and prevent diabetes from developing in some at-risk patients. However, implementing behavioral weight-loss programs in a primary care setting can be a challenge.

Bastyr University's Jennifer Lovejoy, an NIBIB grantee, is trying another approach. She's using cable TV technology to deliver an interactive weight-loss program to patients with type 2 diabetes. Other types of weight-loss programs, delivered *via* the Internet, have been shown to be effective. Unfortunately access to computers and the Internet is limited among low-income individuals and the elderly, two populations at risk for type 2 diabetes and its complications. Lovejoy's project demonstrates that a diet and exercise program can be delivered directly to individuals in their homes using a TV and a special interactive remote control. Blood sugar and body weight are monitored, and individuals can receive and respond to special notices related to their weight management program.

Objectives

- The development and use of low-cost medical technologies and telehealth is supported through NIBIB initiatives.
- Program initiatives targeting underserved populations are initiated to increase their participation in biomedical imaging and bioengineering research.
- Activities and programs are developed to educate underserved populations on the value of imaging and technology development to health care.

Goal 5

An intramural research program with interdisciplinary emphasis.

The intramural research program will engage high-quality research and training in biomedical imaging, bioengineering, and the quantitative sciences. Priorities will focus on specific projects that have broad, national impact and on multidisciplinary programs that complement research in other NIH intramural programs and can't be effectively done in the extramural community.

Strategies

- Implement recommendations of a Blue Ribbon Panel (appendix B) and the NIBIB Advisory Council in establishing the program and actively seek advice from stakeholders during the initial growth of the intramural program.
- Develop intramural research capabilities that are not readily implemented in the extramural community and that leverage and complement existing intramural programs at NIH and other agencies.
- Support training in interdisciplinary research at multiple educational levels that will result in a high impact on health care.

Objectives

- A Scientific Director for intramural research is recruited.
- The administrative infrastructure for the intramural program is established.
- Establish a Board of Scientific Counselors, including experts in the physical and life sciences to provide input into the direction, scope, and productivity of NIBIB's intramural program.
- Unique research programs that build on NIH strengths and complement other NIH intramural research programs are created.
- A strong intramural research training component is established.
- Collaborations between the intramural and extramural research and training programs are in place.

Joint Venture with FDA

A collaboration between NIBIB and the U.S. Food and Drug Administration's Center for Devices and Radiological Health (CDRH) will strengthen efforts by CDRH's Laboratory for the Assessment of Medical Imaging Systems. Key among those initiatives aided by NIBIB resources are:

- development of new approaches for reviewing the massive amounts of data generated by new medical imaging scanners;
- support for research initiatives to improve cardiovascular imaging protocols that are optimized to each individual patient;
- development of methods for the evaluation of software tools for quantifying change in lesion features using CT data sets; and
- development of approaches for the assessment of software programs used in the detection of breast cancer.

Interdisciplinary Research Training

Goal 1

Biomedical research training programs that integrate the physical, engineering, and life sciences.

Interdisciplinary research and career development training programs help develop a cadre of biomedical imaging and bioengineering research scientists who can lead the advancement of these growing scientific fields. NIBIB's support for training programs will help bridge the gaps between the biological, physical, and engineering sciences by attracting and training new students, as well as supporting the training and career development of existing researchers to advance the prevention, diagnosis, and treatment of disease.

Strategies

- Train engineers and physical scientists in biology and medicine and biomedical researchers in the engineering and physical sciences.
- Facilitate career development for physicians and physician scientists in bioengineering and biomedical imaging research.
- Emphasize training in team science.
- Utilize resources and expertise from other agencies and foundations where appropriate.
- Address specific training needs in understaffed disciplines.
- Promote academic curricula development in entrepreneurship, including commercialization, technology transfer, and regulatory topics.
- Engage undergraduate students from multiple disciplines in interdisciplinary research.

Objectives

- The number of physicians, engineers, and scientists conducting biomedical imaging and bioengineering research in the clinical setting is increased.
- A research program for medical residents is established that supports the participation of residents on NIBIB research grants.
- A program is initiated to support the critical transition of postdoctoral researchers to independent investigators.
- Interdisciplinary training and career development programs are created that encompass fundamental research skills and interactions of physical, quantitative, and biomedical scientists.
- Institutional training programs are developed to train a new generation of team-oriented researchers in order to accelerate the pace of technological discoveries.
- Innovative programs are established to support the funding of investigators new to the NIBIB.
- Research opportunities are created that support the participation of undergraduate students in interdisciplinary research teams.

Innovative Interdisciplinary Graduate Training

The goal of NIBIB training programs is to bridge the gap between the biological, engineering, and physical sciences by attracting and training new students, as well as supporting the training and career development of existing researchers to advance the prevention, diagnosis, and treatment of disease.

As new modeling, imaging, and other computational techniques become key tools to further our understanding of complex biological systems, it is increasingly important for biologists to have a clear understanding of the power and limitations of these approaches. Biologists will also benefit from collaborations with individuals from relevant outside disciplines. It is similarly important that physical and engineering scientists develop a deep understanding of the breadth and nature of biological scientific questions. The interplay of these groups will produce many more synergistic alliances than if the groups remain separate.

NIBIB has partnered with the Howard Hughes Medical Institute to support the HHMI-NIBIB Interfaces Initiative, a university-level program that gives Ph.D. scientists the knowledge and skills needed to conduct interdisciplinary research. This new cadre of scientists will be at the forefront of progress in biomedical research which increasingly relies on the input of new ideas, methodologies, and investigative strategies from the physical sciences, engineering, and mathematics.

Another goal of the Interfaces Initiative is to reduce barriers to interdisciplinary graduate science education. Each participating institution is expected to develop integrated courses, laboratory experiences, and other innovative educational mechanisms for graduate trainees with different scientific backgrounds. In addition, member institutions must develop "best practices" models for use by other universities. These examples provide guidance on how to establish or modify academic and administrative structures to facilitate graduate study across disciplines.

All U.S. institutions that grant Ph.D. degrees in appropriate science or engineering disciplines are eligible to apply for support through this initiative.

Goal 2

Increased involvement of underrepresented populations in biomedical research.

The mission of the NIBIB is both expansive and inclusive. To meet the challenges outlined in this plan we need participation of communities that have historically been underrepresented in biomedical and engineering research.

Strategies

- Utilize training programs to attract underrepresented populations to bioengineering and biomedical imaging research careers across the career continuum.
- Develop and expand linkages with minority organizations and professional societies.

Objectives

- Program initiatives targeting underrepresented populations are initiated to increase their participation in biomedical imaging and bioengineering research.
- Interactions between minority institutions/organizations and the NIBIB are established to enhance the development of NIBIB's programs and facilitate participation by NIBIB in meetings, conferences, and other activities targeting minority populations.

Probing Cells and Molecules

When Samuel Achilefu was young, he thought he would be a mathematician because he loved numbers. However, his desire to know why things are the way they are motivated him to study chemistry. Today, as an associate professor of radiology at Washington University School of Medicine, Achilefu uses a multidisciplinary approach to improve optical imaging techniques and illuminate the intricacies of atomic and molecular systems. One area of his research involves developing molecular probes to image cancer. These light beacons detect cancer cells and track their movement, giving researchers a powerful tool to study and treat the disease.

By combining optical imaging with either computed tomography or magnetic resonance imaging scanning, Achilefu hopes to develop a method to noninvasively image diseased tissue at both cellular and molecular levels. Such sensitive imaging could improve both diagnostic and therapeutic options for patients. The molecular probes may allow clinicians to determine the effectiveness of a given treatment within a matter of weeks rather than months, as is often the case with conventional imaging methods.

AREAS OF OPERATIONAL EMPHASIS

Alliances and Partnerships

Goal 1

Strategic alliances that maximize the impact of NIBIB on national and international health care.

Effective alliances and partnerships with NIBIB stakeholders, other NIH Institutes and Centers, other Federal agencies, academia, and biomedical industries are critical to the success of NIBIB's mission of accelerating the applications of novel technologies to health care. Collaborations resulting from these alliances will help maintain relevant state-of-the-art research and development programs, leverage resources among public and private entities, enhance the Institute's image for the lay public, and ensure support of the broad scientific community. Effective alliances will establish the NIBIB as a national leader in multidisciplinary biomedical research and training.

Strategies

- Partner with industry, other NIH Institutes and Centers, Federal agencies, non-profit organizations, and academia for mutual benefit.
- Identify complementary strengths, resources, and objectives by participating in strategic planning with partners.
- Expand and strengthen working relationships with stakeholders and partners.

Objectives

- Joint programs and initiatives are established with industry, NIH Institutes and Centers, academia, other Federal agencies, international organizations, and others.
- Regular and *ad hoc* meetings are held with representatives of technical societies and biomedical industry organizations to plan and coordinate activities and partnerships.
- Topical meetings are held with congressional and advocacy representatives to showcase and explain the impact of NIBIB-supported health care advances.
- Trans-NIH and inter-agency consortia are created that focus on multidisciplinary biomedical research at the interface of the physical and life sciences and enhance communication among the life and quantitative science communities.
- NIBIB staff provides leadership at scientific, engineering, and medical meetings related to the Institute's mission.

NIBIB Policy: Special Consideration for Support of Research that Bridges the Life and Physical Sciences

A major focus of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) since its inception has been the bridging and integration of the life and physical sciences. Over the past few years, this focus has been enforced by Congressional language (e.g., Report Language accompanying the House FY 2004 Appropriations Bill) and has culminated in a "Conference on Research at the Interface of the Life and Physical Sciences: Bridging the Sciences."

Bridging the Gap between the Sciences

The nature of the biomedical sciences requires linkages and communication across disciplines. Recognizing this need, NIBIB seeks input from scientists in a broad range of areas, from biology and medicine to engineering, the physical sciences, mathematics, and computer science. One way NIBIB gathers information is to sponsor forums that bring together researchers in a broad range of disciplines from academia, Federal agencies, foundations, and technical societies.

During the "Conference on Research at the Interface of the Life and Physical Sciences: Bridging the Sciences," sponsored by NIBIB and the National Science Foundation, participants noted a number of opportunities for interdisciplinary collaboration, including addressing global problems such as climate change and emerging diseases, extending our understanding of fundamental biological and physical processes, and integrating biological and physical systems. Many challenges to interdisciplinary partnerships were also discussed, such as inadequate education and training at all career levels, lack of support for high-risk research, and cultural differences across disciplines. Participants suggested that a key to building bridges between disciplines would be creation of a national initiative aimed at bridging the gap between the sciences. This effort would bring together the resources of academia, industry, national laboratories, technical societies, and Federal agencies.

Outreach, Education and Communication

Goal 1

A public that is educated and informed about the value of biomedical technology.

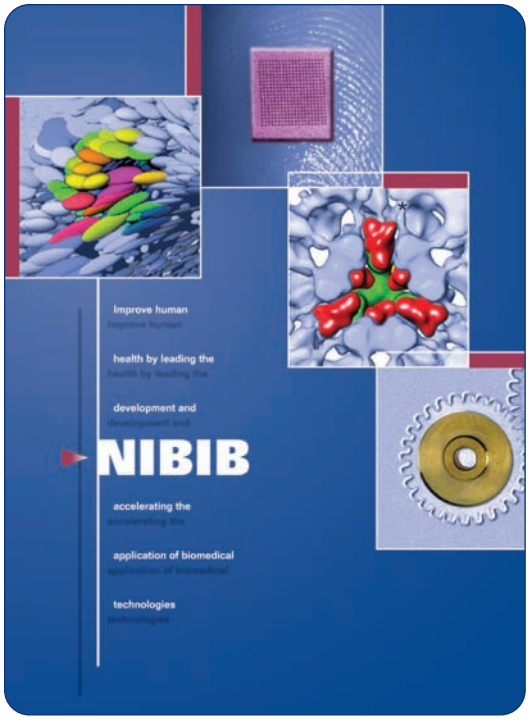
Communicating research findings and health messages to the public is an important component of the NIBIB's mission. This information needs to be disseminated to a wide audience in culturally appropriate ways. To accomplish this, NIBIB is expanding its communication efforts with the general public and the research community. Multiple media are being used to convey these messages, including print materials and fact sheets, the Web, and an exhibit booth.

Strategies

- Communicate and disseminate reliable programmatic information and research advances to researchers, physicians, Congress, and the public.
- Address public concerns about medical technology.
- Collaborate on information dissemination with other NIH Institutes and Centers, Federal agencies, academia, and others.

Objectives

- Expanded print and online information on the health impact of medical technology, including materials in Spanish.
- A grantsmanship tutorial about the NIH and the NIBIB's programs and funding opportunities is developed and presented at multiple venues.
- Briefings for members of Congress and their staff are provided on hot topic issues and the status of NIBIB-supported research.
- Mixed media presentations are created to present culturally appropriate medical technology information to targeted audiences at professional and scientific meetings.
- Publications describing the health benefits associated with advances in medical technology are produced and disseminated.
- Inquiries from the public, stakeholders, and Congress are addressed in a timely and factual manner.

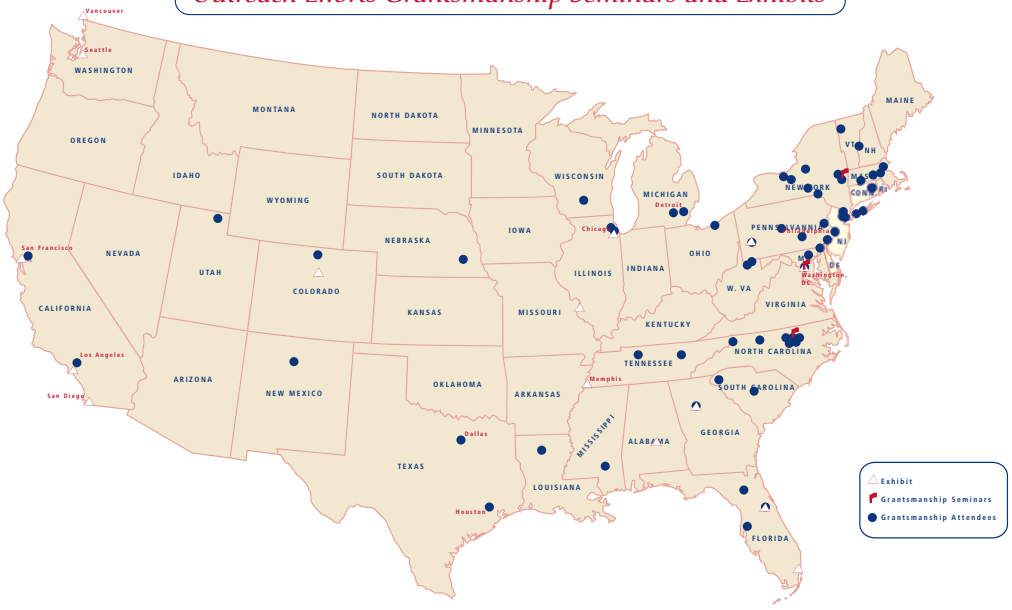


Grantsmanship Seminars

Fulfilling the NIBIB mission requires accessing the resources and capabilities of a segment of the scientific community that traditionally has had little contact with the NIH – the physical, engineering, and computational science communities. Investigators in these fields are often unaware of opportunities to apply their skills and resources to biology and medicine and are typically not familiar with NIH grant application procedures and policies. One of NIBIB's goals is to address these issues for physical scientists and investigators new to the NIH by conducting a series of regional outreach seminars.

NIBIB launched a series of regional Grantsmanship Seminars in the spring of 2005. The objective of this one-day seminar is to provide information on the Institute's funding opportunities in research and training and the NIH application, review, and grant-making processes and policies. The seminars include presentations from NIBIB science program and review staff members and examples of successful grantee experiences with the NIH.

Outreach Efforts Grantsmanship Seminars and Exhibits



Stewardship and Accountability

Goal 1

Proper stewardship of public funds and trust.

The NIBIB is a Federally-funded research Institute and is committed to maximizing the investment of available resources while preserving the highest level of scientific integrity and public accountability.

Strategies

- Make transparent and accountable decisions regarding funding and award administration.
- Make decisions in a way that is consistent with our mission and Strategic Plan.
- Use checks and balances in the administration of grants and contracts.
- Obtain public input in the priority-setting process.

Objectives

- A priority-setting process that includes program reviews, professional societies, patient advocacy groups, and our National Advisory Council is in place.
- An administrative infrastructure and business processes are instituted to ensure appropriate use of public funds.
- Grants management systems for tracking, reporting, and decision-making and financial management systems with audit and reporting measures are utilized.
- NIBIB participates in the NIH Public Trust Initiative.

NIH Public Trust Initiative

In the spring of 2004, Elias A. Zerhouni, M.D., Director of the National Institutes of Health (NIH), announced the establishment of the NIH Public Trust Initiative. In doing so, he stated that his goal is to "improve the public's health through promotion of activities and attitudes that will instill confidence in what we do as a premier biomedical and behavioral research enterprise."

Gaining and enhancing the public's trust is a top priority for all of NIH, one that will require a long-term commitment and partnerships with each of NIH's publics. How and why the NIH conducts and supports research, and the outcomes of that research, should be conveyed in such a manner that everyone can understand and use the information to achieve better health.

SCIENTIFIC DIRECTIONS

The scientific goals, strategies, and objectives outlined in this plan will enable the NIBIB to move forward with a prudent plan over the next 5 years while still retaining the flexibility to respond to discoveries and opportunities. Implementation of this agenda is highly dependent upon economic resources, scientific advances, and competing priorities. The following describes the management philosophy in determining scientifically based budgetary priorities.

To accomplish its mission, the NIBIB will give high priority to the development of new investigators and the recruitment of established investigators from disciplines such as engineering, imaging, computational biology, and the physical sciences into biomedical research. These disciplines historically have not received emphasis in NIH funding.

The Institute will also stress extramural training programs that support the development of interdisciplinary researchers. The NIBIB will pursue programs and actions that encourage and facilitate the development of a strong cadre of interdisciplinary biomedical researchers capable of successfully competing for the NIH investigator-initiated R01 grant mechanisms. A high priority will be an NIBIB success rate for investigator-initiated research that is comparable to the rates for other NIH Institutes. If budgets are limited, the NIBIB will consider focusing resources on investigator-initiated research and adjusting individual grant levels to permit funding of additional awards.

The NIBIB recognizes that multiple investigators working synergistically on a research project can be more effective than individual investigators in solving complex biological or medical problems. Existing integrative programs like the Bioengineering Research Partnership Grants have proven highly effective in this capacity. Planned new programs, such as the Quantum grants, also offer promise as models for developing strong collaborative research efforts that will lead to improvements in health care. The NIBIB will maintain these programs as a priority at their current levels, but will expand them as additional resources become available.

An intramural research program complementary to our extramural program is integral to the long-term success of the Institute. Priority will be given to establishing an interdisciplinary training program that leverages existing intramural research programs at other NIH Institutes while building a modest intramural research program.

Appendix A: NIBIB Submission for the NIH Comprehensive Strategic Plan and Budget to Reduce and Ultimately Eliminate Health Disparities Fiscal Years 2002-2006

Mission/Vision Statement

Public Law 106-580 authorized the establishment of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to provide a research home for the development and application of new technologies and techniques for the delivery of health care. NIBIB brings the research communities of biomedical imaging, bioengineering, and physical sciences together with the life sciences community to advance human health and quality of life and reduce the burden of disease. It is the mission of the NIBIB to improve human health by leading the development of and accelerating the application of biomedical technologies. The Institute is committed to integrating the physical and engineering sciences with the life sciences to advance basic research and medical care. The vision of the NIBIB is to profoundly change health care. NIBIB will push the frontiers of technology to make the possible a reality.

Strategy for Addressing Health Disparities

Since the establishment of the NIBIB, the Institute has focused on building a portfolio and identifying key principles to guide its growth. The Institute does not concentrate on specific health conditions associated with life-span, disease, or anatomical site. It is, however, positioned to identify challenges in medical research that can benefit from bioengineering and bioimaging approaches. NIBIB provides leadership in developing cross-cutting research and training in biomedical imaging and bioengineering, to reduce health disparities, with the ultimate goal of improving the health and well-being of all Americans.

The NIBIB is currently developing a strategic plan that will outline priorities for research, training, dissemination of research findings and community outreach for the next three to five years. The outcome of this process will include specific program plans for improving minority health and addressing health disparities. One broad area of exploration is the potential of various technologies to improve access and enhancing the affordability of medical technologies that improve quality in health care. NIBIB is currently supporting research from at least two initiatives that may contribute to advances in these areas. Another approach may be to investigate the potential for imaging, engineering and the physical sciences to improve prevention, diagnosis, and treatment in the six identified areas that account for the most serious health disparities: infant mortality; cancer screening and management; cardiovascular disease; diabetes; HIV infection/AIDS; and immunization. NIBIB will work collaboratively with other NIH Institutes and Centers and other Federal agencies to optimize impact.

The Institute plans to build upon current efforts to increase participation of underrepresented students and new minority investigators in NIBIB training programs. Recognizing the success of many existing NIH/Federal initiatives, the NIBIB will continue to join and support effective programs to expand opportunities for training in imaging and engineering sciences that target

underrepresented minorities or those engaged in health disparities research. The Institute will conduct a public outreach campaign to increase awareness and participation by members of underrepresented groups in these programs and other training and research programs supported by the NIBIB.

Communicating research findings and health messages to the public is an important component of the NIBIB mission. This information must be broadly disseminated in minority communities in culturally appropriate ways. The NIBIB will expand communication efforts to convey information on the latest advances and applications in biomedical imaging and engineering.

1.0 Areas of Emphasis in Research

1.1 Area of Emphasis One: Medical technologies for the detection, diagnosis and treatment of human diseases and injury

The NIBIB is committed to the development of medical technologies that reduce health disparities. Modern medical technologies are critical for quality health care, yet remain widely unavailable to many patients in poor and underserved communities. The invention and development of low-cost medical devices may provide more widespread use and efficient application of modern medical technologies. Thus, the NIBIB is committed to supporting novel investigations for low-cost medical devices that can be broadly applied to research and treatment of disease and injury. Because many current medical devices used for detection, diagnosis and treatment are expensive and unavailable to some segments of society, the NIBIB plans to stimulate research that will lead to lower cost medical devices. Development of inexpensive, innovative, medical devices is needed, with particular emphasis on early detection and efficient treatment of disease and injury. Cost reductions in high-technology medical devices may lead to reduced health care costs, and consequent reduction of health disparities.

1.1.1 Objective One: Low-Cost Medical Technologies

This objective focuses on the development of low-cost medical technologies that enable wider dissemination of medical imaging devices and engineering technologies.

1.1.1.1 Action Plan

To accomplish the objective of low-cost medical technologies NIBIB will:

- Promote research on the development of new, affordable medical technologies.
- Support cost reductions in existing medical technologies to make them more widely available.

In 2003 NIBIB released a Request For Applications (RFA) directed toward the development of low-cost medical imaging technologies. Twenty-four grants were funded, and the NIBIB continues to support these and additional investigator-initiated applications for low-cost imaging. R21 grantees, funded as part of the low-cost medical imaging initiative, will be encouraged to explore methods for additional funding (e.g., R01 support). R01 grantees will be urged to seek added support from venture capital and industry to advance their research development to commercialization.

1.1.1.2 Performance Measures

1) Funded low-cost imaging grants.

2) Meetings with industry stressing the importance of these efforts.

1.1.1.3 Outcome Measures

1) Number of funded grants.

2) Number of grants that progress to phase II and phase III

1.1.2 Objective Two: Advances in telehealth to reduce health disparities

This objective focuses on the development of telehealth technologies to reduce health disparities by bringing medicine and medical expertise to environments and remote regions that have reduced access to medical diagnostic, planning and treatment technologies and specialists.

1.1.2.1 Action Plan

The Internet is widely available and provides a vehicle for the transmission of medical information (e.g., images and electronic patient records) from underserved areas to major health care centers. NIBIB supports advances in telehealth that will broaden access by underserved populations to high-quality health care. Portable diagnostic devices are capable of recording physiological, biochemical, and diagnostic image data non-invasively in rural and non-hospital settings. Telehealth is defined by the Department of Health and Human Services as "the use of communications technologies to provide and support health care at a distance." Examples include the use of communications to provide patient treatment, often through the transmission of still images or video, and the exchange and distribution of public health information. Issues amenable to technical solutions arise in the diagnosis, treatment, and follow-up with a patient at a distance. The technical feasibility of telehealth applications has been well demonstrated for several specific applications in the past (as reported at the NIH Telemedicine Symposium, March 2001, http://www.nlm.nih.gov/research/telesymp.html). The current need is to generalize remote access technology to be adaptable to a broad range of telehealth applications, to develop mechanisms in which the technology can be integrated seamlessly into the routine of the provider and the patient, and to develop technology for standardizing and incorporating state-of-the-art security protocols for verifying user identities and preserving patient confidentiality.

The main objectives of advancing telehealth to reduce health disparities are demonstrated in the following examples:

- Image based consults involve medical diagnosis or treatment of a patient in a remote clinic, accomplished through the transmission of medical images to a specialist. To facilitate this, NIBIB supports the development of specialized hardware and software for image compression, storage, transmission, and display. NIBIB also supports the design and development of peripheral (non-image) devices that can aid in a remote interactive examination.

- Home-based health care using physiological monitoring devices also benefit from development of low-cost, low-power physiological sensors, wireless technologies, and

inexpensive interactive video for pre-operative or follow-up interactions with a health care provider. Future applications include hand-held or portable digital imaging and display devices. Wearable patient monitors, which are lightweight and non-invasive, long-life batteries, and telemetry hardware and software may also help reduce health disparities.

In 2002, the NIBIB released an RFA and a Small Business Innovative Research and Small Business Technology Transfer Program Announcement (PA) directed toward the development of telehealth technologies. Six grants were funded through these competitions and the NIBIB continues to support these and additional investigator-initiated applications on telehealth technologies. NIBIB's program in telehealth technologies currently supports research in the following areas on health disparities: cancer screening, cardiovascular disease, and diabetes.

1.1.2.2 Performance Measures

1) Funded telehealth grants.

1.1.2.3 Outcome Measures

1) Number of funded grants.

2) Number of grants that progress to Phase II and Phase III.

3) Evidence of products developed as a result of this research.

1.1.3 Objective Three: Support the Development of human tissue engineered model systems to create and evaluate new vaccines

1.1.3.1 Action Plan

Support investigator-initiated applications as indicated by policy guidelines.

1.1.3.2 Performance Measures

1) Funded grants within this area of research.

1.1.3.3 Outcome Measures

1) Number of funded grants.

1.1.4 Objective Four: Support the development of needle-free delivery systems for childhood vaccinations

1.1.4.1 Action Plan

Support investigator-initiated applications as indicated by policy guidelines.

1.1.4.2 Performance Measures

1) Funded grants within this area of research.

1.1.4.3 Outcome Measures

1) Number of funded grants.

1.2 Area of Emphasis Two: Support for inclusion of minorities in clinical studies

The inclusion of individuals from all racial and ethnic groups in clinical studies is critical to the realization of effective interventions for improving health. NIH guidelines for inclusion of women and minorities in clinical studies are designed to achieve this outcome. NIBIB currently supports a number of studies with significant minority representation. The Institute will continue to monitor adherence to these policies by grantees in our portfolio.

1.2.1 Objective One: Ensure that clinical studies supported by the NIBIB adhere to the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research

1.2.1.1 Action Plan

NIBIB staff will continue to track inclusion data and provide guidance on these policies to NIBIB grantees.

1.2.1.2 Performance Measures

Appropriate representation by diverse groups in NIBIB-supported clinical studies and accurate and effective maintenance of inclusion data.

1.2.1.3 Outcome Measures

Maintain appropriate representation of minorities in NIBIB-supported clinical studies.

2.0 Areas of Emphasis in Research Capacity

2.1 Area of Emphasis One: Interdisciplinary Training of Underrepresented Minorities

Training a new cadre of interdisciplinary researchers is an important component of the Institute's mission. In an effort to draw talented researchers into the activities of the Institute, NIBIB is developing new training programs in the biomedical imaging and bioengineering fields as well as adopting existing NIH training mechanisms to meet the needs of the NIBIB extramural community. The Institute's approach is to develop opportunities that will fill critical gaps along the career continuum, while also enhancing the participation of underrepresented populations.

2.1.1 Objective One: Training Programs to Attract Underrepresented Minorities to Bioengineering and/or Biomedical Imaging Research Careers

NIBIB will participate in NIH programs to promote training of underrepresented minorities across the career continuum.

2.1.1.1 Action Plan

This objective will be accomplished by joining several NIH-wide program announcements targeted to underrepresented minorities.

1) The NIBIB is a participant in the NIH Program Announcement (PA-01-079) entitled "Research Supplements for Underrepresented Minorities." This NIH-wide program provides supplements to existing NIH grantees to appoint an underrepresented minority as a trainee on research project grants. Eligibility extends from high school

students through established research investigators. The NIBIB will participate in any reissues of this announcement.

2) We currently participate in the NIH Program Announcement (PA-00-069) entitled "NIH Predoctoral Fellowship Awards for Minority Students (F31)." This program specifically targets underrepresented minorities enrolled in doctoral programs and provides up to 5 years of fellowship support to complete their training.

3) Bioengineering and Bioinformatics Summer Institute (BBSI) Program: This is a joint training program targeting late undergraduate and early graduate students. The goal is to attract individuals to pursue graduate careers in bioengineering and/or bioinformatics. An objective of this program is to attract underrepresented minorities.

4) NIH Institutional Training Programs: The NIBIB joined the trans-NIH program announcement for institutional predoctoral/postdoctoral training grants. Although these programs are not specifically targeted for underrepresented minorities, these programs are required to address the recruitment of underrepresented minorities and track their participation in the training grant.

5) NIBIB supports the Hispanic Association of Colleges and Universities summer internship program to encourage their commitment to bioengineering or imaging careers.

2.1.1.2 Performance Measures

We will track the number of applications received and the number of applications awarded.

2.1.1.3 Outcome Measures

We are developing methods for tracking career progress of trainees supported by our different training programs, including individual and institutional awards.

2.2 Area of Emphasis Two: Research Community Outreach

2.2.1 Objective One: Develop new and expand current linkages with minority organizations and professional societies.

2.2.1.1 Action Plan

NIBIB will develop linkages with minority serving institutions, organizations, and professional societies to increase awareness of NIBIB research and training programs and to increase participation of minority investigators in NIBIB-funded research.

2.2.1.2 Performance Measures

- Track distribution of printed materials targeting minority groups.
- Track NIBIB's participation in minority-focused meetings.

2.1.1.3 Outcome Measures

- Number of linkages with minority organizations and institutions.

3.0 Areas of Emphasis in Community Outreach, Information Dissemination, and Public Health Education

3.1 Area of Emphasis One: Information Dissemination

NIBIB has initiated a comprehensive strategic planning process to identify and address present and future scientific research directions. One of the next steps in our strategic planning effort is to develop a formal process for outlining and conducting outreach and education activities, including the development and dissemination of print and media materials on health disparities or for underserved populations.

3.1.1 Objective One: Increase dissemination of NIBIB information and research advances and applications in ways that are meaningful to target audiences.

3.1.1.1 Action Plan

Communicating research findings and health messages to the public is an important component of the NIBIB mission. This information needs to be disseminated broadly to minority communities in culturally appropriate ways. For example, the NIBIB will provide materials in Spanish when appropriate and host web sites that are accessible to individuals with disabilities. The NIBIB is expanding its communication efforts with the general public and the research community to enhance dissemination of the latest advances and applications in biomedical imaging and bioengineering research. Multiple media are being used to convey these messages, including print materials and fact sheets, the web, and an exhibit booth.

3.1.1.2 Performance Measures

- Develop and disseminate reliable scientific information and research accomplishments to minority institutions and organizations.
- Exhibit NIBIB-funded research activities, opportunities, and scientific advances at appropriate professional and scientific meetings.
- Develop culturally appropriate media opportunities and strategies to broaden awareness and knowledge of NIBIB's mission within minority communities.
- Enhance and expand current print and online (Web) information.
- Translate outreach and education material into Spanish.

3.1.1.3 Outcome Measures

- Number and type of information disseminated.
- Number of documents translated into Spanish.
- Number of meetings at which NIBIB exhibited.
- Web site usage.

Appendix B: National Institute of Biomedical Imaging and Bioengineering Special Advisory Panel for Intramural Programs

I. Executive Summary

The Special Advisory Panel for Intramural Programs met on September 17, 2004 to develop recommendations for the National Advisory Council on Biomedical Imaging and Bioengineering concerning an intramural research program within the National Institute of Biomedical Imaging and Bioengineering (NIBIB).

The Panel was specifically charged with the following questions:

1. Given the financial and space constraints anticipated for the next 2-3 years, should NIBIB attempt to enlarge the focus and scope of its Intramural Research Program beyond its current commitments or delay such growth until it has more substantial resources?
2. If NIBIB should substantially grow the intramural research program, what should be:
   a. The scientific focus and scope of the Program as a whole?
   b. The minimum resources needed to ensure both high quality and opportunity for growth of any new programs, suggested in your answer to (a)? The answer to (b) should consider also the resources needed for the recruitment of a permanent Scientific Director.
3. In an unconstrained environment, what recommendations would you propose for NIBIB's Intramural Research Program?

The Panel received introductory and background information from NIH Deputy Director, Raynard Kington, M.D., Ph.D., NIH Deputy Director for Intramural Research, Dr. Michael Gottesman and NIBIB Director, Dr. Roderic I. Pettigrew. The Panels received additional briefings about NIBIB activities, associated programs and potential collaborations.

The Panel arrived at a consensus supported by a super majority of Panel members.

1. The Panel recommends that NIBIB support the Intramural Research Program but within the available funding in the current budget and the FY 2005 President's Budget proposal.
2. The Panel recommends that NIBIB explore using its limited intramural funds primarily to expand training opportunities, at the interface of bioscience, technology, engineering, mathematics, physics and computer science and that the training opportunities focus at the postdoctoral level.
3. The Panel recommends that NIBIB recruit a fulltime Scientific Director to oversee the development of the envisioned training programs and provide direction for planning an intramural research program should additional funding become available.
4. The Panel recommends that NIBIB develop strategies for establishing and expanding industrial collaborations.

5. Given the Panel's conclusion that sufficient funds are not available at present or in the foreseeable near term to expand the Intramural Program, it did not address the issues in its charge relating to the potential scientific focus and scope of such a program.

II. Introduction and Background

At the request of Roderic I. Pettigrew, Ph.D., M.D., Director, National Institute of Biomedical Imaging and Bioengineering (NIBIB), a Special Advisory Panel for Intramural Programs was constituted and met on September 17, 2004. The purpose of the panel is to provide recommendations to the National Advisory Council on Biomedical Imaging and Bioengineering (NACBIB) and to the Director of the National Institute of Biomedical Imaging and Bioengineering on the planning and development of an intramural research program within the NIBIB.

The Panel was provided with background materials including the NIBIB mission and vision statements and definition of scope. The Panel received background materials about the FY 2004 NIBIB budget and budget breakdown by category, the proposed FY 2005 NIBIB budget proposed by the President and additional statistical and financial information about the NIH, which are included in Appendix B in this report.

III. Panel Meeting, September 17, 2004

The Panel met for one full day on September 17, 2004. Panel members attending included John Linehan, Ph.D. (Co-Chair), James Thrall, M.D. (Co-Chair), Kenneth Dill, Ph.D., N. Reed Dunnick, M.D., Michael Feld, Ph.D., Katherine Ferrara, Ph.D., Sam Gambhir, M.D., Ph.D., Michael Phelps, Ph.D., Paul Yock, M.D., Barbara J. McNeil, M.D., Ph.D. and Frank C. Yin, M.D., Ph.D. attended as liaisons to the National Advisory Council for Biomedical Imaging and Bioengineering. Panel members Shirley Jackson, Ph.D. and Robert Langer, DSC were unable to attend, although Dr. Langer visited the NIBIB the preceeding day and provided his perspective.

NIH Deputy Director Raynard Kington, M.D., Ph.D. welcomed the members of the Special Advisory Panel for Intramural Programs. Dr. Kington asked the group to consider what benefit an Intramural Program can provide beyond the broad base of extramural research already supported by the NIH and NIBIB. How can the NIBIB Intramural Program enhance existing programs across the NIH and how can it best utilize the new Clinical Center?

Michael Gottesman, M.D., Deputy Director for Intramural Research provided an overview of the intramural programs at NIH. He noted that intramural research accounts for approximately 9.5% of the total NIH budget. Most Institutes have intramural programs of variable size and on the whole they are considered successful scientifically. Dr. Gottesman offered four criteria for an intramural research program and supported the thesis that high-risk research can be best done in the NIH intramural environment. The four criteria are:

1. Innovative – not run-of-the mill or difficult to support because of the conservative nature of peer review.
2. Resource intensive – research requiring high tech and expensive equipment.
3. Long-term research that may encompass clinical trials lasting as long as 20 to 30 years.
4. Team science, which Dr. Gottesman asserted, was easier to do in the Intramural Program than in the academic setting.

Dr. Gottesman presented four general models that could be used by NIBIB in considering the development of an Intramural Research Program:

1. Complement and enhance ongoing research in another part of the NIH Intramural Program, for example, the development of ligands for PET imaging.
2. Support training across the NIH by supporting Fellowship Programs in Bioimaging and Bioengineering like the Bioengineering Summer Program and the NIST combined fellowships.
3. Insert programs into existing Intramural Programs, for example, Dr. Pettigrew's lab is co-located with Dr. Balaban's lab.
4. Create a free standing program with its own critical mass but requiring substantial financial, human and space resources all of which are in short supply. Dr. Gottesman noted that new intramural research space on campus is not likely to be available until the 5 to 10 year time frame.

Dr. Pettigrew reviewed the mission and vision of the NIBIB and discussed the questions posed to the Special Advisory Panel in the context of the NIBIB budget. He noted that the FY 2005 President's Budget requests approximately $300 million for NIBIB. The intramural budget was based at $3 million in FY 2004 and is slated to increase to $7.7 million based on the FY 2005 President's Budget. Of this, approximately $4 million of the intramural funds are uncommitted for FY 2005. Dr. Pettigrew noted that intramural budgets are determined by each institute and center and vary widely across the NIH.

Dr. Pettigrew presented a summary of the growth in the number of grant applications to NIBIB since its inception and related data depicting the success rates for extramural research grant (R01s) applications across the NIH including NIBIB. The number of applications to NIBIB increased 400% from FY 2002 to FY 2003 and by an additional 200% from FY 2003 to FY 2004. This growth is in the context of less than a 4% per year increase in the NIBIB budget. Consequently, the success rate for investigators applying for extramural research grants from the NIBIB is the second lowest among the NIH institutes and centers. It is expected that the success rate will decrease from 19.3% in FY 2003 to approximately 16.8% in FY 2004.

Dr. Pettigrew presented summary data comparing expenditures for intramural programs across the NIH both in terms of actual dollars and as a percentage of the total budget. He noted that NIBIB is at the low end with respect to both dollars expended and percentage expenditure of the total budget. He noted that growth in the support for the Intramural Program and NIBIB would have the consequence of further reducing the success rate among extramural applicants for NIBIB grants.

The Special Advisory Panel received additional briefings about NIBIB activities, associated programs and potential collaborations as follows:

Current status of intramural activities overview – Peter Kirchner, M.D., Acting Associate Director for the Intramural Program, NIBIB

Overview of the joint CDRH/NIBIB Laboratory for Assessment of Medical Imaging Systems – Kyle J. Myers, Ph.D.

Biomedical Engineering Summer Internship Program – Robert J. Lutz, Ph.D.

Overview of Existing Bioengineering Programs at NIH – Richard Leapman, M.D.

Overview of Bioimaging Research at the NIH – Robert S. Balaban, Ph.D.

Overview of Bioimaging Research in the Radiology Department at the Clinical Center – the Radiology and Imaging Sciences Program – King Li, M.D.

Overview of Cartilage Tissue Engineering at NIAMS – Rocky Tuan, Ph.D.

Overview of NIST Resources/Commitment for Collaboration – Angela R. Hight-Walker, Ph.D.

Members of the Panel engaged the speakers to understand the interactions that NIBIB has established within the NIH and with other government agencies including the FDA and NIST.

IV. Special Advisory Panel Deliberations

After the presentations by Drs. Kington, Pettigrew and Gottesman and the briefings on current NIBIB activities and interactions, the Special Advisory Panel and the liaison members to the National Advisory Council for Biomedical Imaging and Bioengineering continued meeting in closed session. The Panel reviewed the questions in the Panel's charge in light of the information available on current and future funding for intramural and extramural research, current intramural activities and the current status of the full range of activities involving NIBIB.

The Panel arrived at a consensus point of view supported by a super majority of Panel members. The Special Advisory Panel offers the following recommendations and observations:

1. The Panel recommends that NIBIB support the Intramural Research Program, but within the available funding in the current budget and the FY 2005 President's Budget proposal.

   Current ongoing intramural work and collaborations within the NIH and with other government agencies is excellent. Opportunities exist to further strengthen and expand these activities without undermining the ability of NIBIB to build a strong constituency of extramural investigators.

   Absent substantial additional appropriations of funds beyond those in the current and proposed budget, the only source of funds to significantly grow the Intramural Program would be through a reduction of resources now committed to the Extramural Program. Reducing extramural funding in the face of low and declining success rates for extramural grant applicants potentially puts the NIBIB at a disadvantage in attracting outstanding investigators including young scientists to submit proposals with damaging long-term consequences.

2. The Panel recommends that NIBIB explore using its limited intramural funds primarily to expand training opportunities. In particular, the uniqueness of the mission of the NIBIB at the interface of bioscience, technology, engineering, mathematics, physics and computer science highlights the importance of training across these multiple disciplines, bringing non-traditional students into the biological sciences. The Panel recommends that the focus of these training activities should be at a postdoctoral level. These training programs could become signature initiatives of the NIBIB distinguishing it among the other institutes at NIH.

3. The Panel recommends that NIBIB recruit a fulltime Scientific Director to help accomplish the mission of bringing science and engineering together with biology, to oversee the development of the envisioned unique training programs and to further provide insight and

direction for development of an intramural research program over the longer term as the funding landscape changes. The Scientific Director would help establish an NIBIB presence on campus, work with the Director to look for and exploit opportunities for collaboration and, leveraging the modest monies available, be in a position to take advantage of other unanticipated opportunities as they might arise.

4. The Panel believes that industry has a unique role to play in the fulfillment of NIBIB's mission and the Panel recommends that NIBIB develop strategies for industrial collaborations.

5. Given the Panel's conclusion that sufficient funds are not available at present or in the foreseeable near term to expand the Intramural Program, it did not address the issues in its charge relating to the potential scientific focus and scope of such a program.

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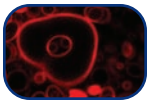

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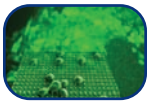

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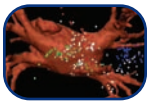

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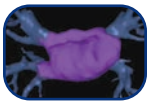

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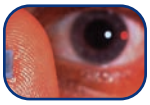

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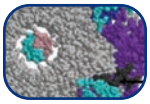
P. 10 (Top right) NIBIB stock photo



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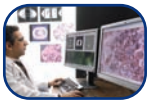

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